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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Jon S. Wilson

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06/23/2009

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EXAMINER

VU, QUYNH-NHU HOANG

ART UNIT

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DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/797,363	Applicant(s) WILSON ET AL.	
	Examiner QUYNH-NHU H. VU	Art Unit 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 May 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 32-50 and 52-61 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 32-50, 52-61 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Response to Amendment

Amendment and Request for Continued Examination (RCE) filed on 05/27/09 have been entered.

Claims 32-50, 52-61 are present for examination.

Claims 1-32 and 51 are cancelled.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 32-34, 42, 47, 50, 52, 54, 58, 60 are rejected under 35 U.S.C. 102(b) as being anticipated by Pourchez (US 6,001,079).

As noted that, Applicant defines the term “proximal” referred to those portions of a catheter inserted into an area of a patient’s body such as a blood vessel; and the term “distal” for connection to a fluid exchange device, such as a dialysis machine or the like (Specification on page 11, lines 7-15). Meanwhile, Pourchez discloses opposite way. However, to accommodate with the claimed invention, the proximal portion 5 is referred as portions of a catheter inserted into the blood vessel, and the distal portions 11 of catheters referred as portions of catheter that outwardly from the patient’s body.

Pourchez discloses a multi-lumen catheter comprising:

(a) a one-piece multi-tube portion 1 having a plurality of integrally formed lumens 2, 3; the multi-lumen tube portion having a proximal end 5 having a proximal end 13A, 14A, distal end at portion 6;

(b) a distal portion 6 comprising a plurality of distal single-lumen tubes 2, 3; each distal single-lumen tube having a proximal end and a distal end, the proximal end of each distal single-lumen tube being permanently and directly connected to the distal end of the multi-lumen tube portion, without a hub, such that the lumen of each distal single-lumen tube is in fluid communication with one of the plurality of lumens of the multi-lumen tube portion;

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(c) a proximal portion comprising a plurality of single-lumen tube, each proximal single lumen tube 2, 3 having a distal end 13A, 14A and a proximal end 6, the distal end of each proximal single lumen tube being permanently and directly connected to the proximal end of the multi-lumen tube portion such that the lumen of each proximal single lumen tube is in fluid communication with one of the plurality of lumens of the multi-lumen tube portion; and

a plurality of extension members 13, 14 configured at a proximal end thereof to be selectively attachable to one of the distal single lumen tubes and configured at a distal end thereof for connection to a fluid exchange device 9.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 38, 49 and 56 are rejected under 35 U.S.C. 103(a) as being unpatentable over

Pourchez.

Regarding claims 38 and 56, it is well-known in the catheter art that the catheter tube is flexible and soft plastic tube with fusible material characteristic.

Regarding claim 49, Pourchez shows that the proximal single lumen tubes are two in number and have longitudinal axes which intersect an included angle in a free state. Pourchez does not specifically disclose the included angle being range from about 10-30 degrees.

It would have been obvious to one having ordinary skill in the art at the time of the invention was made to obtain the included angle range from 10-30 degrees, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art.

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Claims 35, 39-41, 43, 57, 59, 61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pourchez in view of Schweikert et al. (US 6,719,749).

Regarding claims 35, 39-41, 43, 57, Pourchez discloses the invention substantially as claimed. Pourchez does not clearly show a connector adapted to receive and hold the distal end of the distal single lumen tubes; the distal single lumen tubes having a substantially round cross-section over at least a portion of their length (claims 39, 57) or substantially D-shaped (claim 40) or round cross-section over at least a portion of their length and the proximal single-lumen tubes having a substantially D-shaped cross-section over at least a portion of their length.

Schweikert discloses similarly to the claimed invention. Schweikert further discloses a connector 50 adapted to receive and hold the distal end of the distal single lumen tubes. Schweikert further discloses that the distal single lumen tubes having a substantially round cross-section or other shapes such as D-shaped (Figs. 2 or 3B, col. 7, lines 4-11); the proximal single lumen tubes having a substantially D-shaped or other shapes over at least a portion of their length (Fig. 3A, 3C, col. 7, lines 12-19).

It would have been obvious at the time the invention was made to a person having ordinary skill in the art to modify the device of Pourchez with a connector, as taught by Schweikert, in order to receive and hold the distal end tube with other tubes or other medical device. The shapes of lumen for improving the speed flow of liquid.

Regarding claims 43, 59, Pourchez discloses the invention substantially as claimed. Pourchez does not suggest a stabilizing cuff affixed to an outer portion of the multi-lumen tube.

Schweikert discloses a stabilizing cuff 44 affixed to an outer portion of the multi-lumen tube.

It would have been obvious at the time the invention was made to a person having ordinary skill in the art to modify the device of Pourchez with a stabilizing cuff, as taught by Schweikert, in order to allow subcutaneous tissue or other body tissue depending upon the application of the catheter device to grow into the cuff.

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Regarding claim 61, Pourchez discloses the invention substantially as claimed. Pourchez does not suggest plurality of selectively attachable connector hubs, each connector hubs being configured to be selectively attachable to the distal end of one of the distal single -lumen tubes.

Schweikert discloses connector hubs 48 being configured to be selectively attachable to the distal end of the distal single-lumen tubes and being configured for selective connection to a fluid exchange device (hemodialysis device).

It would have been obvious at the time the invention was made to a person having ordinary skill in the art to modify the device of Pourchez with connector hubs, as taught by Schweikert, in order to connect the tubes with dialysis equipment.

Claims 36-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pourchez in view of Schon (US 6,682,519) and Smith, III (US 4,832,687).

Pourchez discloses the invention substantially as claimed. Pourchez does not disclose that a connector comprises means for attaching the connector to a trocar; a sheath that may be disposed over at least a portion of the distal end of the two distal single-lumen tubes and at least a portion of the connector.

Schon discloses a similar catheter device and further states that the subcutaneous tunnels are forming using a tunneling device (not shown) such as a stainless steel trocar, which, attaches to a first proximal end 59 (equivalent to distal end of claimed invention) of the first proximal portion 48 (equivalent to first distal portion of claimed invention), col. 11, lines 1-15. Schon further discloses that a second incision is made and a tunneling device such as a trocar is passed into the incision and out through the skin at the point of catheter insertion creating a subcutaneous tunnel. The catheter is attached to the tunneling device (trocar) and pulls back through the skin tunnel, col. 2, lines 42-49. In other words, there is a connector located and attached between the trocar and the proximal tube of catheter. Schon also discloses that the introducer sheath is positioned by placing a dilator/trocar device inside of the introducer sheath and passing both the dilator and the introducer sheath together into the vessel, col. 1, lines 54-59.

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Smith discloses a subcutaneous tunneling device comprising: a rod/trocar 12 comprising a connector 22 attached to the distal portion of catheter 26.

It would have been obvious at the time the invention was made to a person having ordinary skill in the art to modify the device of Pourchez, with the connector and the introducer sheath, trocar connected with the catheter tubes, as taught by Schon and Smith, in order to provide the connection between the trocar and the catheter during the subcutaneous tunnel procedure.

Claims 44-46, 53, 55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pourchez in view of Schweikert et al. and further in view of Markel (US 5,624,413).

Pourchez in view of Schweikert discloses the invention substantially as claimed. Pourchez disclose extension member 11. Meanwhile, Schweikert discloses that each extension member 50, 52 comprising a mating compression fitting 50 and a tube portion 52, a distal end of the mating compression fitting is rigidly attached to a proximal end of the tube portion and the mating compression fitting allows fluid communication there through. Schweikert further discloses the fitting 48 which may be slidable along the extension tubes 38, 39, but quick connects, either by snap-fit, screw thread or other suitable closure, preferably screw thread as show in lines A of Fig. 1.

Neither Pourchez nor Schweikert disclose that the mating compression fitting is attached to a cannula.

Markel discloses a similar catheter system comprising a each extension member comprising a mating compression fitting (including 88, 90) and a tube portion 92, wherein a proximal end of the mating compression fitting (including 88, 90) is rigidly attached to a cannula 98, a distal end of the mating compression fitting is rigidly attached to a proximal end of the tube portion and the mating compression fitting allows fluid communication between the cannula 98 and the tube portion 92; wherein the mating compression fitting further comprises a thread connection portion (located between element 86 and 88), this limitation is similar to limitation of claim 55.

It would have been obvious at the time the invention was made to a person having ordinary skill in the art to modify the device of Pourchez in view of Schweikert, with the compression fitting attached to

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the cannula, as taught by Markel, in order to connect the extension tube with other catheter tube for fluid communication through the catheter.

Claim 48 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pourchez in view of Herweck et al. (US 5,197,976).

Pourchez in view of Schweikert discloses the invention substantially as claimed. Pourchez does not disclose the single-lumen tube includes indicia indicating a discrete flow path through the catheter.

Herweck discloses that the tube structure can include identifying indicia, such as colored lines to distinguish each structure from other (col. 2, lines 45-50 or in claim 5 of the Invention of Herweck). For example, the device of Herweck comprises two different flow paths (phantom arrow) in Fig. 1, the tube structure can be different colored lines so that the user can distinguish between the in or out flow direction of fluids.

It would have been obvious at the time the invention was made to a person having ordinary skill in the art to modify the device of Pourchez, with an indicia, as taught by Herweck, in order to distinguish between the flow path of fluid lines.

Response to Arguments

Applicant's arguments with respect to claims 32-50, 52-61 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Quynh-Nhu H. Vu whose telephone number is 571-272-3228. The examiner can normally be reached on 6:00 am to 3:00 pm.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nicholas D Lucchesi/

Quynh-Nhu H. Vu

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Supervisory Patent Examiner, Art Unit 3763

Examiner
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